



# Animal Welfare Institute

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September 23, 2013

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
(Submitted via regulations.gov website)

RE: Docket #FDA 2000-N-0190

To Whom It May Concern:

I am writing on behalf of the Animal Welfare Institute (AWI) and our supporters to offer comments on the Food and Drug Administration's (FDA) Draft Guidance for prevention of *Salmonella* Enteritidis (SE) for egg producers providing outdoor access to their hens.

Since its founding in 1951, AWI has been dedicated to reducing animal suffering and promoting the welfare of all animals, including animals used in agriculture. As a part of our mission, we promote humane farming systems and work to advance legislative and regulatory efforts to improve the conditions of farm animals. We also administer our own animal welfare food certification program, Animal Welfare Approved (AWA), through which we work with scientists and farmers to set high farm animal care standards. All of the farmers certified by our program provide pasture access for their animals and are, therefore, potentially impacted by the Draft Guidance.

## **1. Enclosed porches do not constitute "the outdoors."**

We appreciate that FDA decided against requiring testing of the outdoor environment. However, we strongly disagree with the determination that enclosed porches—which are merely part of the poultry house—are to be considered an acceptable form of outdoor access. This is objectionable for two reasons. First, enclosed porches are not "the outdoors" and do not give birds access to soil and direct sunlight. And second, these porches typically can only accommodate a very small percentage of the house's flock, while the regulations of the National Organic Program require that *all* animals be provided access to the outdoors. Organic egg producers who only provide porches for outdoor access are violating the organic regulations. Furthermore, these producers are being given a market advantage through the ability to sell their organic eggs for less than producers who meet the regulations and actually provide hens with outdoor access. Therefore, we request that the "Indoor Area with Porch" be removed as a housing style acceptable for organic production.

## **2. The risk from wild birds is not adequately substantiated.**

We support the recommendations regarding limiting contact with animals that are known salmonella carriers, including rodents and flies. The scientific literature demonstrates that these animals are carriers of SE and therefore present a risk for transmission of the disease to egg-laying hens and other farm animals. However, we challenge the strength of the science supporting the recommendations to avoid contact between wild birds and egg-laying hens. We are not convinced that the research cited by the Draft Guidance prove that wild birds are common vectors of SE.

The study conducted in Croatia by Cizek et al. found that on one farm with SE in calves, salmonella was isolated from 8 out of 31 birds, but on a farm with no salmonella in animals, only 2 out of 2,186 birds tested positive. The report concluded the study “shows a relationship between contamination of the environment with SE and the incidence in wild birds.” However, the study does not conclude that wild birds give farmed animals salmonella, and in fact it is possible that the transfer was in the reverse direction, and scavenging birds received SE from the farm animals.

While another study (Craven et al.) did conclude that there is a risk of SE transmission from wild to domestic birds, the conclusion was based on a fairly small sample of only four farms, two of which had no salmonella positives from wild birds during initial testing. Tizard’s (2004) study conducted in Texas is the only report that indicated salmonella bacteria are commonly found in the intestines of wild birds. However, this certainly is not the same as saying wild birds commonly transmit salmonella to commercial poultry. In fact, after reviewing other research findings this report concludes that “under some circumstances the infection [salmonella] can spread to domestic and wild animals. It is important to note however that the literature does not show evidence that wild birds are a significant source of infection for domestic poultry.”

Consequently, the assumption that wild birds present a major salmonella threat to domestic poultry does not appear to be supported by the research referenced in the Guidance, and we recommend that the document be revised accordingly.

## **3. Other, more significant risk factors are not addressed.**

While the risk of transmission from wild birds is not well documented by the research cited, other research showing that farms with outdoor access are likely to be at low risk for salmonella is ignored by the Guidance. Multiple European studies analyzing SE prevalence rates demonstrate that organic and free range farms have a low incidence of salmonella, while salmonella can be more common with caged production. For example, in 2004-2005, the European Food Safety Authority analyzed more than 5,000 samples for salmonella contamination and found cage production to be associated with a higher risk of salmonella contamination than production methods allowing for outdoor access. Whereas 25 percent of caged houses tested positive for SE, less than 10 percent of organic houses did. (See European Food Safety Authority, Report of the Task Force on Zoonoses Data Collection on the Analysis of the Baseline Study on the Prevalence of Salmonella in Holdings of Laying Hen Flocks of *Gallus Gallus*, 2007.)

We recommend that the Guidance be revised to address other, more significant risks to SE transmission, including unsanitary and crowded conditions, older buildings, caged production, and forced molting.

**4. Exclusion should only be necessary during a disease outbreak or period of demonstrable risk.**

The information offered by the Guidance can be useful to farmers who provide outdoor access for their birds. However, for the reasons noted above, AWI does not feel that the low risk of SE transmission between wild birds and commercial poultry justifies a recommendation that all producers regularly exclude contact between wild and domestic birds. Farmers should be encouraged to take basic biosecurity precautions that are considered good practice against all transmittable disease and implement measures to exclude contact with wild birds when a specific, demonstrable risk is shown.

Thank you for considering our comments. Do not hesitate to contact me at 202-446-2146 or by email at [dena@awionline.org](mailto:dena@awionline.org) if I can answer any questions or provide additional information.

Sincerely,

A handwritten signature in black ink that reads "Dena Jones". The signature is written in a cursive, flowing style.

Dena Jones  
Farm Animal Program Manager